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EXAMINER	
GRAZIER, NYEEMAH	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,954	KURUKULASURIYA ET AL.	
	Examiner	Art Unit	
	Nyeemah Grazier	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3-8, 15-19, and 1-2 and 9-14 (in part)* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-2 and 9-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/21/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

DETAILED ACTION

I. PRIORITY

This application claims benefit of provisional application serial number 60/437,132 filed on December 30, 2002.

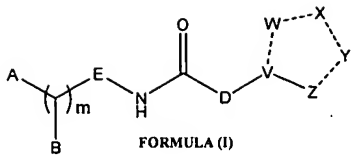
II. ACTION SUMMARY

Claims 1-14 are currently pending in the instant application and are subject to the required restrictions and elections as described below. Claims 15-19 are non-elected claims and are therefore withdrawn from consideration and examination. Furthermore, Claims 1-2, in-part and 9-14, in part are objected to as containing non-elected subject matter. Claims 3-8 are withdrawn as containing non-elected subject matter. 37 C.F.R. § 1.142(b).

III. RESTRICTION

The Markush group set forth in the claims includes both independent and distinct inventions, and patentable distinct compounds or species within each invention. However, the instant application discloses and claims a plurality of patentable distinct inventions far too numerous to list individually. Moreover, each of these inventions contain a plurality of patentable distinct compounds, also far too numerous to list individually. Restriction to one of the following Inventions is required pursuant to 35 U.S.C. § 121, wherein an Invention is a set of patentable distinct inventions of a broad statutory category.

I. Claims 1-14, drawn to a product of Formula (I), classified in various subclasses of various classes such as class 544, subclass 235, class 548, subclasses 131and 234, for example.



FORMULA (I)

II. Claim 15, drawn to a method of antagonizing the glucagon receptor, classified in class 514, subclass 377.

III. Claims 16-19, drawn to a method of treatment, classified in class 514, subclass 377.

Markush Claims

A provisional election of a species is required because the Markush-type claims of the instant application include distinct independent inventions. Restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. See In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); See also Ex Parte Hozumi, 3 USPQ2d 1059 (BPAI 1984). Absent evidence that subject matter of the Markush-type claim lacks unity of invention, the Office may not merely "refuse to examine that which applicants regard as their invention." See M.P.E.P. § 803.02; In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Additionally, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C.

§103. **Therefore, in addition to an election of one of the abovementioned Inventions, restriction is further required under 35 U.S.C. § 121.**

If Invention I is elected, election of a single species is further required, including an exact definition of each substitution on the base molecule, Formula (I), wherein a single member at each substituent group is selected. For example, in the instant application, the base molecule of Formula (I) has substituent B, where "B is selected from the group consisting of H, F, OH, alkoxy and -N(RaRb)- wherein Ra and Rb are each independently selected the group consisting of hydrogen, alkyl, alkylcarbonyl, alkylsulfonyl alkoxyalkyl, cycloalkyl, cycloalkylcarbonyl, cycloalkylsulfonyl, cycloalkylalkyl, heterocycle, heterocyclealkyl, heterocyclecarbonyl and heterocyclesulfonyl." (Instant Application SN 10/743954, p.44, ll. 8-11.) Applicant must select a single substituent representing B and in the case where B is cyclic, substituents and variable positions for the substituents. This process is repeated for each variable so that a single compound is identified.

If Invention III is elected, then election of a specific method of use is required. For example: A method of treating:

A. type 2 diabetes;

B. type 1 diabetes;

C. syndrome X;

D. obesity, etc.

Additionally if Group III is elected and an election of a particular disease, then a further election of the symptoms of that disease is also required. For example: A method of treating type 2 diabetes wherein said symptoms are selected from:

A. hyperglycemia,

B. obesity;

C. hypertension, etc.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound. The elected compounds should be similar that they will encompass the same inventive concept and reduction to practice. The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound and the entire scope of the invention encompassing the elected compound as defined by common classification.

A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds, which are so similar, within the same inventive concept and reduction to practice. Markush claims require sufficient support in the disclosure for each member of the Markush group. See MPEP § 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the core structure as the selected species must be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

Invention I-III are related as product and process of use of the product. However, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product M.P.E.P. § 806.05. In the instant case the method of treating type 2 diabetes as recited in instant Claim 15 (Invention II) can be accomplished with products other than the product of Formula (I); and with regards to antagonizing glucagons receptors, substituted benzimidazoles and pyridylphenyls. See e.g., CHANG, L. L., et al., "Substituded Imidazoles as Glucagon Receptor Antagonists," *Bioorg. & Med. Chem.. Letrs.*, 11:2549-2553 (2001).

Inventions II and III are related as methods of uses. However, Inventions II and III are independent and distinct. Specifically, Invention II is directed to a different use, namely antagonizing a receptor; yet, Invention III is directed to treatment of diseases and their symptoms.

Additionally, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Lack of restriction would impose a serious burden on the Examiner. Thus, based on the abovementioned rationale, the restriction as set forth in the instant application is proper.

In sum, each Group listed above has a diverse chemical structure, different chemical properties, different modes of action, and different effects and reactive conditions and is therefore recognized in the art as being distinct from one another. MPEP §§ 806.04, 808.01. Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The rebuttable presumption, that similar chemical structures behave similarly, may be overcome by scientific reasoning or evidence showing that the

structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Advisory of Rejoinder

The Examiner has required restriction between a product and method of use claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of

prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Pursuant to M.P.E.P. § 821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Telephone Inquiry

During a telephone conversation with Johanna Corbin, Esquire on April 26, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14, directed to a product. Ms. Corbin also elected Example 6 as a species of the genus. Claims 15-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant is reminded that he/she is required to affirm this election when responding to this Office Action.

IV. ELECTION

Scope of the Elected Subject Matter Based on Example 6

Applicant's telephonic election with traverse of the compound N-{4-[(2Z)-2-[(4-bromophenyl)imino]-3-(4-tert-butylcyclohexyl)-1,3-oxazolidin-4-yl]benzoyl}-beta-alanine, example 6, in response to the requirement to restrict the products of Formula (I) is

acknowledged. Therefore the elected invention for search and examination is the products of Formula (I) as recited in instant **Claim 1** wherein:

"**A**" is CO_2H;

"**B**" is selected from the group consisting of H, F, OH, alkoxy;

"**m**" is 0 -2;

"**n**" is 0 - 2;

"**D**" is aryl;

"**E**" is $(CH_2)_n$;

"**V**" is $-(CR_c)-$ wherein $\mathbf{R_c}$ is selected from the group consisting of hydrogen, alkyl, alkoxy, alkoxyalkyl, cycloalkyl, cycloalkyloxy, cycloalkylalkyl;

"**W**" is selected from the group selected from $-C(R_dR_e)-$, O-, -S-, -S(O)-, and $-S(O)_2-$; and $-(R_d)N-$;

"**X**" is $-C=N(R_j)-$;

"**Y**" is selected from a group consisting of $-C(R_kR_m)-$, $-(R_k)N-$, -O-, -S-, -S(O)-, and $-S(O)_2-$;

"**Z**" is $-C(R_pR_q)-$; and

$\mathbf{R_d}$, $\mathbf{R_e}$, $\mathbf{R_j}$, $\mathbf{R_k}$, $\mathbf{R_m}$, $\mathbf{R_p}$ and $\mathbf{R_q}$ are selected from the group consisting of hydrogen, alkyl, alkoxy, alkoxyalkyl, cycloalkyl, cycloalkyloxy, or cycloalkylalkyl.

Scope of Withdrawn Subject Matter Not Drawn to Example 6

The remaining subject matter of claims 1, 2, and 9-12 that is not drawn to the above invention and the subject matter of Claim 1 stands withdrawn under 37 CFR § 1.142(b) as being

for non-elected subject matter. The compounds are not within the elected invention, which are independent and distinct from the elected invention and do not have utility with the elected compound and are therefore withdrawn by way of restriction.

Compound of Claims 3-8 and 13 are withdrawn by way of restriction are the compounds of Formula (I) wherein:

"**A**" is tetrazole;

"**B**" is selected from the group consisting of -N(RaRb)- wherein

Ra and Rb are each independently selected from the group consisting of hydrogen, alkyl, alkylcarbonyl, alkylsulfonyl alkoxyalkyl, cycloalkyl, cycloalkylcarbonyl, cycloalkylsulfonyl, cycloalkylalkyl, heterocycle, heterocyclealkyl, heterocyclecarbonyl and heterocyclesulfonyl;

"**D**" is heteroaryl;

"**V**" is –N-;

"**X**" is –C(O)-, -C(O)C(R_fR_g)-, -C(R_fR_g)C(O)-, -C(S)-, -C(R_fR_g)-, -C(R_fR_g)C(R_iR_j)-, -S(O)- and –$S(O)_2$-;

"**Z**" is –C(R_pR_q) C(R_sR_t)-; and

R_d, R_f, R_g, R_i, R_j, R_p, R_q R_s, and R_t, are selected from the group consisting of heterocycle, heterocycleakyl, heterocycleoxy, and heterocyclealkoxy.

The abovementioned compounds are withdrawn from consideration as being non-elected subject matter. The withdrawn compounds contain distinct substitutions such as heterocycle, heterocycleakyl, heterocycleoxy, and heterocyclealkoxy, etc., which differ significantly in structure and function. This structural and elemental variety of substitutions is exemplified by their classifications in the U.S. classification system. For example: thiazoles are classified in

548/146+ while pyridines are classified in 546/249+,etc. Therefore the compounds are withdrawn as being non-elected subject matter that differs materially in structure and composition.

V. OBJECTIONS

Claim Objection

Claims 1,2 and 9-14 are objected to as containing non-elected subject matter. To overcome this objection, Applicant must amend instant Claims 1,2 and 9-14 to reflect the elected invention as stated above.

VI. CONCLUSION

Claims 15-19 are withdrawn from further consideration by the Examiner because Claims 15-19 are drawn to a non-elected invention. 37 C.F.R. § 1.142(b). **Claims 3-8** are withdrawn from further consideration by the examiner as being drawn to non-elected subject matter. **Claims 1-2, and 9-14** are objected to as containing non-elected subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

Nyeemah Grazier

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